No. 24-30673

UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
Plaintiff-Appellant,

v.

LIZ MURRILL, IN HER OFFICIAL CAPACITY AS ATTORNEY GENERAL OF LOUISIANA,
Defendant-Appellee,

LOUISIANA PRIMARY CARE ASSOCIATION,
Intervenor Defendant-Appellee.

On appeal from the United States District Court
for the Western District of Louisiana
No. 6:23-cv-00997
District Judge Robert R. Summerhays

UNOPPOSED MOTION FOR LEAVE TO FILE BRIEF BY AMERICAN HOSPITAL ASSOCIATION, LOUISIANA HOSPITAL ASSOCIATION, 340B HEALTH, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS AS *AMICI CURIAE* IN SUPPORT OF DEFENDANT-APPELLEE AND INTERVENOR DEFENDANT-APPELLEE

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Pursuant to Federal Rule of Appellate Procedure 29(a)(3), movants American Hospital Association, 340B Health, Louisiana Hospital Association, and American Society of Health-System Pharmacists respectfully move the Court for leave to file a brief as *amici curiae* in support of Defendant-Appellee and Intervenor-Appellee. Defendant-Appellee and Intervenor-Appellee consent to the filing of this *amicus* brief, and Plaintiff-Appellant Pharmaceutical Research and Manufacturers of America does not oppose the filing of this brief.

I. INTEREST OF MOVANTS

Movants include three non-profit organizations with members in Louisiana that receive 340B discounts for drugs that they purchase, many of which are dispensed through contract pharmacies, and one organization that represents pharmacists, many who are located in Louisiana, who serve patients in hospitals, health systems, ambulatory clinics, and other healthcare settings that benefit from the 340B program. Movants and their members are committed to improving the health of the communities they serve through the delivery of high-quality, efficient, and accessible health care. The discounts provided by the 340B program are essential to achieving this goal. Movants therefore have a strong interest in the success of Louisiana's legislative efforts to protect the 340B program.

II. MOVANTS' BRIEF WILL BE USEFUL TO THE COURT'S CONSIDERATION OF THIS APPEAL.

Movants' brief complies with Federal Rule 29 and contains valuable insight to inform the Court's consideration of the merits of this appeal. As representatives of 340B covered entities and pharmacists serving patients, movants are uniquely positioned to explain the critical role of contract pharmacies, which have been used by covered entities since the beginning of the 340B program. Movants are also qualified to explain how the onerous contract pharmacy restrictions that drug companies began to impose in 2020 resulted in significant harms to patients and 340B providers, which operate on razor-thin margins to provide care to individuals with low incomes. Further, movants' brief explains why the challenged Louisiana statute, which requires drug companies to honor the contract pharmacy relationships of Louisiana covered entities, is an essential healthcare regulation within the State's historic police powers to promote public health.

III. CONCLUSION

Based on the foregoing, movants respectfully request that the Court grant this motion for leave to file a brief as *amici curiae* in support of Defendant-Appellee and Intervenor-Appellee and accept for filing the *amicus curiae* brief submitted contemporaneously with this motion.

Date: April 18, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on April 18, 2025, the foregoing Unopposed Motion for Leave to File Brief of American Hospital Association, 340B Health, Louisiana Hospital Association, and American Society of Health-System Pharmacists as *Amici Curiae* in Support of Defendant-Appellee and Intervenor-Appellee was filed electronically and has been served via the Court's ECF filing system in compliance with Rule 25(b) and (c) of the Federal Rules of Appellate Procedure on all registered counsel of record.

/s/ William B. Schultz
Counsel for Amici Curiae

CERTIFICATE OF COMPLIANCE

This motion complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d)(2) because it contains 380 words, as counted by Microsoft Word, excluding the parts of the motion excluded by Federal Rule of Appellate Procedure 32(f). This motion complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared using Microsoft Word in 14-point Times New Roman font.

/s/ William B. Schultz
Counsel for Amici Curiae

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SUPPLEMENTAL CERTIFICATE OF INTERESTED PERSONS

Pharmaceutical Research & Manufacturers of America v. Murrill, No. 24-30673

In addition to the persons and entities listed in Plaintiff-Appellant's Certificate of Interested Persons, undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

Amici Curiae

American Hospital Association

340B Health

Louisiana Hospital Association

American Society for Health-System Pharmacists

Amici are all non-profit organizations, none of which has a parent corporation nor issues stock.

Attorneys for *Amici Curiae*

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Date: April 18, 2025

/s/ William B. Schultz
William B. Schultz
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INTEREST OF *AMICI CURIAE*[1]

Amici and their members are committed to improving the health of the communities they serve through the delivery of high-quality, efficient, and accessible health care. The discounts provided by the 340B program are essential to achieving this goal. *Amici* therefore have a strong interest in the success of Louisiana's legislative efforts to protect the 340B program.

The **American Hospital Association** (AHA) represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations nationwide. AHA members are committed to helping ensure that healthcare is available to and affordable for all Americans. AHA promotes the interests of its members by participating as *amicus curiae* in cases with important and far-ranging consequences for their members, including cases related to the 340B program.

340B Health is a national, not-for-profit organization founded in 1993 to advocate for 340B hospitals—a vital part of the nation's healthcare safety net. 340B Health represents over 1,600 public and private nonprofit hospitals and health systems participating in the 340B program.

[1] No party's counsel authored this brief in whole or in part. No one other than *Amici* or their counsel contributed any money to fund its preparation or submission. The parties do not object to the filing of this brief.

The **Louisiana Hospital Association** has worked for the betterment of Louisiana hospitals for almost 100 years. It represents more than 150 individual hospital members, including many that participate in the 340B program.

The **American Society of Health-System Pharmacists** (ASHP) is the largest association of pharmacy professionals in the United States. ASHP advocates and supports the professional practice of pharmacists in hospitals, health systems, ambulatory care clinics, and other settings spanning the full spectrum of medication use. For over 80 years, ASHP has championed innovation in pharmacy practice; advanced education and professional development; and served as a steadfast advocate for members and patients.

INTRODUCTION

Five years ago, nearly 40 drug companies, including members of Appellant-Plaintiff Pharmaceutical Research and Manufacturers of America (PhRMA), broke with decades of precedent and suddenly refused to ship drugs purchased by 340B hospitals to contract pharmacies. The federal government believed this was unlawful and sought to require manufacturers to continue delivering these drugs to contract pharmacies on the same terms to which they delivered those drugs to 340B in-house hospital pharmacies.[2]

[2] *See, e.g.*, Letter from Dep't of Health & Hum. Servs., Health Resources & Servs. Admin. Administrator C. Johnson to AbbVie, Inc. Vice Pres., U.S. Market Access C. Compisi (Oct. 17, 2022), https://perma.cc/TC4W-5KWL.

The drug companies fought that effort tooth and nail. In lawsuit after lawsuit, they argued that the federal government could not interfere with their contract pharmacy restrictions. At no point did the drug companies describe their contract pharmacy policies as price restrictions. Instead, they insisted that their policies were permissible because: (1) they were *delivery* restrictions,[3] and (2) the 340B statute had absolutely nothing to say about *delivery*. The drug companies won. *See Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024) (Section 340B is "silent about delivery conditions"); *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 703, 707 (3d Cir. 2023) (Section 340B's "text is silent about delivery" and "[l]egal duties do not spring from silence.").

Now comes the whiplash. Banking those wins, PhRMA and its members reversed course in this litigation. PhRMA now contends that Louisiana's law requiring shipment to contract pharmacies regulates price, not delivery. And as part of that *volte-face*, PhRMA now insists that States cannot fill the federal statutory gap that its members spent years fighting for in sister circuits. PhRMA's heads-I-win-tails-you-lose argument is as shameless as it is meritless.

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[3] *E.g.*, Novartis Opening Brief at 4, *Novartis Pharms. Corp. v. Johnson*, No. 21-5299, Doc. 1949831 (D.C. Cir. June 8, 2022) ("Section 340B . . . is *silent* as to whether manufacturers must deliver those drugs to contract pharmacies.") (emphasis added); AstraZeneca Opening Br. at 4, *AstraZeneca Pharms. L.P. v. U.S. Dep't of Health & Hum. Servs.*, No. 22-01676 (3d Cir. July 21, 2022) ("Section 340B is 'silent' on the role of contract pharmacies under the program. That silence means the statute does not impose contract pharmacy obligations on manufacturers.").

This history is important—and not just because it exposes the hypocrisy in PhRMA's legal position. It also reminds the Court *why* Louisiana chose to step into the federal statutory void. Put simply, Louisiana acted because PhRMA, its member drug companies, and the federal courts all but invited it to.

Faced with the drug industry's unprecedented assault on Louisiana's health care safety net and the acknowledged gap in federal law, the Louisiana legislature passed Act 358, the "Defending Affordable Prescription Drug Costs Act," by an overwhelming 135-2 vote. Act 358 does only what PhRMA and the federal courts said the *federal* law did not do—regulate the delivery of 340B drugs. *See* La. Stat. Ann. § 40:2884 (2023).

The primary issue here is whether Louisiana, exercising its historic police power over health and safety, can fill the gap in the federal 340B statute and regulate the delivery of 340B drugs (purchased by 340B hospitals) to contract pharmacies. It can. And despite what PhRMA would now have this Court believe, the Louisiana statute *does* regulate delivery and *does not* regulate the 340B price. The price of 340B drugs continues to be set by federal law, and Louisiana's law only affects *where* the 340B drugs (purchased by 340B hospitals) are shipped and stored for later dispensing to 340B patients. It is, in essence, a non-discrimination provision. Act 358 allows Louisiana hospitals to choose where 340B drugs are to be delivered, rather than letting drug companies discriminate in favor of in-house pharmacies.

Put differently, Louisiana is merely exerting its independent state "sovereignty" to regulate drugs that "pass[] within [its] own territory." *Zyla Life Scis. LLC v. Wells Pharma of Houston LLC*, No. 23-20533, --- F.4th ----, 2025 WL 1076889, at *7 (5th Cir. Apr. 10, 2025) (internal quotation marks omitted). Exercising its "traditional prerogative," *id.*, the State seeks to ensure that drugs (prescribed to *Louisiana* residents[4]) shipped to pharmacies that *Louisiana* hospitals contract with are treated on the same terms as drugs shipped directly to *Louisiana* in-house hospital pharmacies. PhRMA's attempt to prevent Louisiana from legislating about the delivery of drugs to contract pharmacies for residents physically located within its state borders, bought by hospitals within its state borders, simply because Act 358 "touches" on something that federal law also regulates, cannot be squared with this Court's most recent conflict preemption precedent and, more importantly, foundational "principles of federalism." *Id*. at *6, 7.

In this litigation, PhRMA does not dispute three aspects of the 340B program. *First*, drug companies must deliver 340B drugs to in-house pharmacies at 340B hospitals. *Second*, the 340B statute is silent about delivery. *Third*, the 340B price is set by federal law—not Louisiana's statute. The 340B price of a drug is exactly the

[4] *See* La. Stat. Ann. § 40:2882(5) (narrowly defining "pharmacy" to ensure that "residents who are provided pharmacy care shall be physically located in this state").

same if it is sold to a 340B hospital for delivery to its in-house pharmacy or for delivery to a contract pharmacy.

Act 358 regulates only one thing. Under that law, the purchaser of the drugs (a Louisiana 340B hospital) remains the same. The federally-established 340B price of those drugs remains the same. The 340B hospital's patient remains the same, whether the patient receives the drug from the in-house or contract pharmacy. The *only* difference—and the *only* thing the Louisiana law regulates—is the literal address where the drug is delivered. Act 358 merely requires that drug companies deliver 340B discounted drugs purchased by 340B hospitals to the hospital's contract pharmacies *on the same terms* as they sell those drugs to 340B hospitals with in-house pharmacies. This arrangement had been in place for almost 30 years before the drug industry's sudden U-turn in 2020. All Louisiana's law does is restore that decades-old arrangement by filling the gap in federal law that PhRMA and its members fought for in earlier litigation.

The district court's well-reasoned opinion rejected PhRMA's efforts to squeeze 340B hospitals and upheld Louisiana's lawful exercise of its police power over matters of health and safety. This Court should affirm.

FACTUAL BACKGROUND ON THE IMPORTANCE OF CONTRACT PHARMACY ARRANGEMENTS IN LOUISIANA

PhRMA and its member drug companies spend page after page maligning the 340B Program and the covered entities that rely on it. Needless to say, it is in their

financial interest to do so. For them, every 340B drug they refuse to deliver to a Louisiana contract pharmacy is an additional profit line on their balance sheets.

But this is not how the Supreme Court has viewed the program. As Justice Kavanaugh wrote for a unanimous Supreme Court just a few years ago: "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 738 (2022). And more important here, the Louisiana legislature, with an unbiased interest in protecting its citizens, hospitals, and pharmacies, shares the Supreme Court's view of the Program. When enacting Act 358, the Louisiana legislature rejected the drug companies' efforts to denigrate the 340B Program and those who rely on it.

For good reason. The contract pharmacy arrangements that PhRMA's members honored for almost 30 years helped sustain hospitals and their patients. Nationwide, a quarter of hospitals' 340B benefit comes from drugs dispensed at contract pharmacies.[5] In Louisiana, *at least 90 percent* of some hospitals' 340B benefit comes from drugs dispensed using contract pharmacies. For example, *the entirety* of Allen Parish Hospital's 340B benefit comes from drugs dispensed at

[5] 340B Health, *Restrictions on 340B Contract Pharmacy Increase Drug Company Profits but Lead to Lost Savings, Patient Harm, and Substantial Burden for Safety-Net Hospitals* 8, https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_March_2023.pdf.

contract pharmacies. At least two other members of the Louisiana Hospital Association (LHA) have reported that between 90 and 100 percent of their 340B benefit derives from the use of contract pharmacies.

Contract pharmacy arrangements are especially important because fewer than half of 340B hospitals operate in-house pharmacies.[6] Even fewer—only one in five 340B hospitals—have in-house "specialty" pharmacies, which many insurers require for the dispensing of "specialty" drugs. These drugs are typically used to treat chronic, serious, or life-threatening conditions, and are generally priced much higher than non-specialty drugs.[7] Thus, 340B hospitals typically *must* contract with at least one specialty pharmacy outside of its in-house pharmacy.[8] Denied these and

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[6] 340B Health, *Drugmakers Pulling $8 Billion Out of Safety-Net Hospitals: More Expected as Growing Number Impose or Tighten 340B Restrictions* 2, https://www.340bhealth.org/files/Contract_Pharmacy_Financial_Impact_Report_July_2023.pdf.

[7] Adam J. Fein, Drug Channels Institute, *Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?* (Dec. 12, 2019), https://www.drugchannels.net/2019/12/insurers-pbms-specialty-pharmacies.html; Specialty Drug Coverage and Reimbursement in Medicaid, HHS Office of Inspector General, https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000255.asp.

[8] 340B Health, *supra* note 5, at 7 (citing Adam J. Fein, Drug Channels Institute, *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers* (Mar. 2022); Fein, *supra* note 6, at 12).

other 340B savings associated with contract pharmacies, 340B hospitals have been forced to cut critical programs and services.[9]

340B savings help Louisiana patients in a variety of ways. To take just one example, 340B providers such as Savoy Medical Center in Mamou and InclusivCare in Jefferson Parish testified before the Louisiana legislature that they use 340B savings to support door-to-door transportation for patients who otherwise would have to rely on bicycles or limited public transportation, or who would tragically forgo needed medical care. Similarly, Woman's Hospital in Baton Rouge uses its 340B benefit to fund the delivery of medicines directly to patients at home. Without the 340B savings that flow from contract pharmacy arrangements, these vital programs are at risk.[10]

In these ways and others, contract pharmacy arrangements allow Louisiana's 340B providers to buy drugs at 340B prices to be delivered closer to where their patients live. A significant portion of the population that 340B hospitals serve live in rural communities. Their patients may live more than 100 miles from an in-house pharmacy. This is true for 340B providers like Lake Charles Memorial Health System, which serves a five-parish area covering more than 5,000 square miles.

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[9] *Id.*, 340B Health at 2, 5.

[10] 340B Health, *340B Health Annual Survey 2022: Vital 340B Supported Services Threatened as Manufacturer Restrictions Cut Into Savings* (Jul. 2023), https://www.340bhealth.org/files/340B_Health_Survey_Report_2022_FINAL.pdf.

Although not required to do so, many Louisiana hospitals pass the 340B discount directly on to patients—including those who otherwise could not afford their medications. One of LHA's members reported that, through these direct discounts, its "uninsured patients paid an average of $7.77 for retail prescriptions and $48.05 for specialty medications, compared to the non-340B price of $78.13 and $3,937.10, respectively." This was possible only because the drug company honored the contract pharmacy arrangement. Without the 340B benefit they obtain from drugs dispensed at community pharmacies, these hospitals, which typically operate with razor thin (and often negative margins), report that they will have to curtail these vital programs or eliminate them entirely.

ARGUMENT

As the district court held, PhRMA's claims are meritless. *First*, Louisiana's law is not preempted because Congress did not create or occupy any field through its 340B legislation, nor does it conflict with the 340B statute. At bottom, PhRMA contends that whenever Congress creates a detailed federal program, that comprehensiveness wrests traditional police power from the States. That has never been the rule in our federal system. To the contrary, as the Eighth Circuit explained, "[p]harmacy has traditionally been regulated at the state level, and [courts] must assume that absent a strong showing that Congress intended preemption, state statutes that impact health and welfare are not preempted." *PhRMA v. McClain*, 95

F.4th 1136, 1144 (8th Cir.), *cert. denied*, 145 S. Ct. 768 (2024) (citing *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 972 (8th Cir. 2021)); *see MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1023 (5th Cir. 1994). For this reason, courts that have considered the issue, including the Eighth Circuit and the district court below, have routinely rejected preemption claims regarding materially similar state laws. *See, e.g.*, *PhRMA v. McClain*, 95 F.4th at 1143–45; *Novartis Pharms. Corp. v. Fitch*, 738 F. Supp. 3d 737, 747 (S.D. Miss. July 1, 2024); *AstraZeneca Pharms. LP v. Fitch*, No. 1:24-cv-196-LG-BWR, 2024 WL 5345507, at *4–9 (S.D. Miss. Dec. 23, 2024); *Novartis Pharms. Corp. v. Bailey*, No. 2:24-cv-04131-MDH, 2025 WL 489881, at *2–4 (E.D. Mo. Feb. 13, 2025).[11]

Second, the district court correctly found that Act 358 is not void for vagueness. The commonly-used term "interfere" is easily understood. PhRMA's arguments to the contrary do not meet the high bar required to prove that statutory language is unconstitutionally vague.

[11] The only court to conclude that the drug manufacturers were likely to succeed on the merits of their preemption claim based its ruling on a fundamental misunderstanding of the 340B statute and program. *PhRMA v. Morrissey*, --- F. Supp. 3d ---, Nos. 2:24-cv-00271, 2:24-cv-00272, 2:24-cv-00298, 2024 WL 5147643 (S.D. W. Va. Dec. 17, 2024). As explained *infra* at 18-19, this Court should reject that flawed analysis and follow the consistent approach of other courts around the country.

I. ACT 358 IS NOT PREEMPTED BY FEDERAL LAW.

"'The purpose of Congress is the ultimate touchstone' of pre-emption analysis." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978)). In every preemption case, "and particularly in those in which Congress has 'legislated in a field which the States have traditionally occupied,'" *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996), courts "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress[,]" *City of Columbus v. Ours Garage & Wrecker Serv., Inc.*, 536 U.S. 424, 432 (2002)). PhRMA has the burden to show that Congress intended to preempt Act 358. *See PhRMA v. Walsh*, 538 U.S. 644, 661–62 (2003). Unlike state laws that intrude into uniquely federal areas such as immigration and foreign relations,[12] Act 358 is presumptively *not* preempted. PhRMA therefore must demonstrate Congress's "clear and manifest purpose" to supersede Louisiana's historic authority to regulate in the public health arena, *Lohr*, 518 U.S. at 485 (citation omitted), which it cannot do.

[12] *See, e.g.*, *Arizona v. United States*, 567 U.S. 387 (2012); *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363 (2000).

A. Congress Did Not Create or Occupy a Field When It Established the 340B Program.

Field preemption occurs only in narrowly defined instances, "when federal law occupies a 'field' of regulation 'so comprehensively that it has left no room for supplementary state legislation.'" *Murphy v. Nat'l Collegiate Athletic Ass'n*, 584 U.S. 453, 479 (2018) (citation omitted). Indeed, "[t]he subjects of modern social and regulatory legislation often by their very nature require intricate and complex responses from the Congress, but without Congress necessarily intending its enactment as the exclusive means of meeting the problem." *N.Y. State Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405, 415 (1973). Thus, the Supreme Court has rejected "the contention that pre-emption is to be inferred merely from the comprehensive character" of federal provisions. *Id.* If it did, every time Congress created a federal program, it would create an exclusively federal field into which States cannot intrude. But that is not the law. *Id*. And with the 340B program, "a detailed statutory scheme was both likely and appropriate, completely apart from any questions of pre-emptive intent." *Id.* PhRMA cites *no authority* other than the comprehensiveness of the statute to support the notion that Congress intended to create (or occupy) this purported 340B "field."[13] Accordingly, its field preemption claim fails.

[13] PhRMA continues to rely heavily on *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011). The district court persuasively explained why *Astra* is inapposite. *PhRMA v. Murrill*, Nos. 6:23-cv-00997, 6:23-cv-01042, 6:23-cv-01307, 2024 WL

B. Act 358 Does Not Conflict with the 340B Statute.

"In arguing conflict preemption, Plaintiffs' re-urge most of the same arguments urged with respect to their field preemption claims." *PhRMA v. Murrill*, 2024 WL 4361597, at *8 Nos. 6:23-cv-00997, 6:23-cv-01042, 6:23-cv-01307, 2024 WL 4361597, at *8 (W.D. La. Sept. 30, 2024). These re-packaged arguments fail for the same reasons.

In essence, PhRMA tries to transform the federal statute's silence about delivery into an intentional congressional decision to preempt state regulation. That cannot be. *E.g.*, *Chinatown Neighborhood Ass'n v. Harris*, 794 F.3d 1136, 1143 (9th Cir. 2015) ("Silence, without more, does not preempt—'a clear and manifest purpose of pre-emption is always required.'") (citation omitted); *Camps Newfound/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 616 (1997) (Thomas, J., dissenting) ("Even where Congress has legislated in an area subject to its authority, our pre-emption jurisprudence explicitly rejects the notion that mere congressional silence on a particular issue may be read as preempting state law."). Thus, the district court put it well when it held that "if Section 340B does not address

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4361597, at *7 (W.D. La. Sept. 30, 2024). Put simply, the *Astra* Court's hesitance to allow "potentially thousands of" private parties to sue to correct "errors in manufacturers' price calculations" has no bearing on whether *States* can fill gaps in federal law regarding the delivery of 340B drugs. *Astra,* 563 U.S. at 114. Indeed, the only mention of preemption in *Astra* is in a footnote concerning a different federal program, the Medicaid Drug Rebate Program. *Id.* at 120 n.5.

contract pharmacies or the relationship between covered entities and their contract pharmacies, a state statute that specifically addresses contract pharmacies cannot conflict with Section 340B." *PhRMA v. Murrill*, 2024 WL 4361597, at *8.

When conducted properly, a conflict preemption analysis requires parties to demonstrate that the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). This is a "high threshold," *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 607 (2011), and PhRMA comes nowhere close to meeting it. The 340B statute was passed to help covered entities "reach[] more eligible patients and provid[e] more comprehensive services." *Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 822 (D.C. Cir. 2020) (internal quotation omitted), *rev'd on other grounds sub nom.*, *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724 (2022). Act 358, in turn, enables 340B providers to continue to benefit from contract pharmacy arrangements and thereby offer expanded healthcare to their patients. Therefore, not only does Act 358 not interfere with Congress's 340B scheme; it "furthers" it. *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 82 (1987); *PhRMA v. McClain*, 95 F.4th at 1144–45; *PhRMA v. Murrill*, 2024 WL 4361597, at *9 ("Act 358 arguably *advances* Congress' objectives with respect to the Section 340B program.").

C. The Lone District Court to Find Preemption Did So on the Basis of a Misunderstanding of the 340B Statute and Program.

To support its arguments, PhRMA relies on the Southern District of West Virginia's preliminary injunction ruling. But that decision was based on a flawed interpretation of the federal 340B statute and how the program operates. It not only ignores the presumption against preemption, *Lohr*, 518 U.S. 470, but at times reads as if that presumption is inverted. It is therefore telling that this outlier decision carried no weight with a Mississippi district court, which explicitly rejected the decision's reasoning just a few days later. *AstraZeneca v. Fitch*, 2024 WL 5345507, at *9 (refusing to "disregard mainstream decisions and the Eighth Circuit's ruling in *McClain* without clear precedential support").

The West Virginia district court erred in several critical respects. *First*, it wrongly concluded that its State statute regulates 340B drug price and not delivery. This finding cannot survive this Court's recent analysis in *Zyla Life Scis. LLC v. Wells Pharma of Houston LLC*. Neither the West Virginia court nor PhRMA disputes that the federal government sets the purchase price for 340B drugs. Act 358 regulates only *where* the drug must be shipped for a Louisiana resident. And, as this Court confirmed, "one of the fundamental features of sovereignty is the power to regulate 'every thing that passes' within one's own territory." *Zyla Life Scis.*, 2025 WL 1076889, at *7 (citation omitted).

Here, Act 358 simply bars drug companies from discriminating between

delivery locations for residents "physically located in" *Louisiana*. *See* La. Stat. Ann. § 40:2882(5). Act 358 requires drug companies to let 340B hospitals within State borders determine the appropriate shipping address for 340B patients living within its borders. It makes no difference that this delivery non-discrimination provision "touches" federal law, *id.*, "expressly incorporates federal law into state law," *id.* at *1, or indirectly addresses the same "primary conduct" of the federal 340B statute (*i.e.*, providing discounted drugs to 340B covered entities), *id.* at *7; *see also id.* ("States may generally regulate the same conduct the Federal Government does.").[14] If Louisiana cannot require drug companies to deliver drugs purchased by 340B hospitals at their contract pharmacies *on the same terms as* they deliver those drugs to in-house hospital pharmacies, then we are truly entering the world of an "all-powerful federal overlord." *Id.* at *7.

[14] PhRMA cannot distinguish *Zyla* by arguing that the state law at issue there was identical to the relevant federal statute for two important reasons. *First*, *Zyla* specifically explained that "[i]f regulating the same primary conduct in different ways does not upset federal enforcement prerogatives, it follows *a fortiori* that regulating it in parallel ways does not either." *Id.* at *8; *see id*. at *7 ("So not only did the State and Federal Governments regulate the same conduct; they did so in different ways. Still, the Supreme Court held there was no conflict."). *Second*, PhRMA's argument is even more aggressive than the one rejected in *Zyla*. Here, it is agreed that the federal law is silent as to delivery. Thus, Louisiana isn't even regulating "concurrently" with federal law. It is filling a gap in the 340B statute consistent with the "'historic primacy of state regulations of matters of health and safety.'" *Id*. at 2. (quoting *Lohr*, 518 U.S. at 485).

Further, the West Virginia court's decision rested on a fundamental misunderstanding of the replenishment model. It reasoned that, "[b]ecause the drug is already in the hands of the contract pharmacy even before the patient arrives at the pharmacy, the question is not about delivery of the drug. The question is only about what price the pharmacy and the covered entity will pay the manufacturer for the replenished drug upon distribution of the 340B Program eligible one." *PhRMA v. Morrissey*, 2024 WL 5147643, at *6. That is not true. The replenishment model is an inventory management system that tracks patient and drug data to ensure that 340B hospitals only pay the 340B price for drugs received by their eligible patients. The 340B hospital would pay that exact same price if it were replenishing its own inventory after a patient received the drug at its pharmacy. Thus, replenishment at the 340B price would happen whether the 340B drug is delivered to the hospital's pharmacy *or* the hospital's contract pharmacy. And that is all the Louisiana law addresses—*where* drug companies must ship those drugs for in-State Louisiana patients to receive them.

Indeed, by regulating the delivery of 340B drugs, Louisiana is not expanding the number of patients eligible for 340B pricing under federal law. Nor is it altering the 340B price itself. Operating within the precise metes and bounds of the 340B statute—which is silent as to delivery and contract pharmacies—Louisiana is protecting its in-State hospitals' freedom to decide *where* they want drugs that they

have purchased to be delivered. If a Louisiana hospital wants to buy a particular medication, the drug companies will ship to an in-house hospital pharmacy without restriction. Act 358 simply ensures that those companies *also deliver* those drugs to the pharmacies with which its in-State hospitals have contracts, thereby making it easier for in-State hospitals to reach their patients closer to where they actually live. Nothing in federal law forbids Louisiana from making that policy decision.

Ultimately, the parties are only fighting about logistics. There is no dispute that 340B hospitals are entitled to buy covered drugs at the federally-mandated price for their patients. The parties only disagree about the delivery address, where a hospital warehouses a drug, and back-end inventory management. The federal statute is concededly silent about these logistical subjects. Louisiana's law, by contrast, addresses *only* these subjects. For this reason, the district court in *this* case—and not the district court in West Virginia—got it exactly right when it held that the price "discounts are set by the federal government, not the State of Louisiana or Act 358. Act 358 addresses only contract pharmacies, a matter that is not addressed in Section 340B." *PhRMA v. Murrill*, 2024 WL 4361597, at *9.

Second, the West Virginia district court misapprehended the true purpose of the 340B statute. Drawing on language from a congressional report, numerous courts have held that the "program was intended to enable certain hospitals and clinics 'to stretch scarce Federal resources as far as possible, reaching more eligible patients

and providing more comprehensive services.'" *Am. Hosp. Ass'n v. Hargan*, 289 F. Supp. 3d 45, 47 (D.D.C. 2017), *aff'd sub nom.*, *Am. Hosp. Assoc. v. Azar*, 895 F.3d 822 (2018) (quoting H.R. Rep. No. 102–384, pt. 2, at 12 (1992)). Thus, the statute's provisions regarding diversion and duplicate discounts do not create "twin" statutory purposes. *PhRMA v. Morrissey*, 2024 WL 5147643, at *6. That court's misunderstanding of the actual purpose of the 340B statute infected its entire conflict preemption analysis, which, when done properly, turns on identifying whether a state law stands as an obstacle to Congress' *actual* purpose. Yet again, the district court in this case got it right when it identified the true purpose of the 340B program and concluded that Louisiana's law "arguably advanced" it. *PhRMA v. Murrill*, 2024 WL 4361597, at *9.

Third, based on its clear misunderstanding of the federal 340B audit process, the West Virginia court incorrectly found obstacle preemption on the grounds that by restricting drugs companies' ability to demand claims data as a condition for ordering 340B drugs the State statute "hampers the ability of drug manufacturers to formulate the 'reasonable cause' necessary to conduct an audit[.]" *PhRMA v. Morrissey*, 2024 WL 5147643, at *7. Under the federal statute and HRSA guidance, however, when a manufacturer wishes to conduct an audit of a covered entity, it must demonstrate "reasonable cause," defined broadly to mean that a reasonable person could believe that a covered entity may have violated a requirement of section

340B(a)(5) (A) or (B) of the PHS Act. *See* Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg, 65,406, 65,409 (Dec. 12, 1996).

HRSA's guidance and practice confirm that the "reasonable cause" showing that a drug manufacturer must make to obtain authority to audit a covered entity is a modest one. According to long-standing HRSA guidance, manufacturers can satisfy this standard in various ways, including by pointing to "[s]ignificant changes in quantities of specific drugs ordered by a covered entity and complaints from patients/other manufacturers about activities of a covered entity[.]" 61 Fed. Reg at 65,406. Critically, we are not aware of an instance when HRSA has *ever* required the claims or utilization data that the pharmaceutical companies now demand to initiate an audit. Nor has HRSA ever expected that a manufacturer would have access to claims data until *after* it conducted an audit. Tellingly, PhRMA *cannot point to a single instance* of HRSA rejecting a manufacturer's audit plan due to the absence of claims data, and we are aware of none.

The district court's reasoning turns the audit process upside down. The audit process designed by federal statute does not contemplate companies requiring hospitals to *prospectively* turn over massive amounts of data as a precondition to receiving 340B discounts. Instead, the statutory audit process is meant to *retrospectively* measure a covered entity's compliance *after* 340B transactions have occurred. Indeed, longstanding HRSA guidance forbids manufacturers from

"condition[ing] the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions." Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110, 25,113 (May 13, 1994); *see* Health Res. & Servs. Admin., 340B Drug Pricing Program Notice, Release No. 2011 – 1.1, Clarification of Non-Discrimination Policy (2012) (same).[15]

At bottom, for more than thirty years, the same agency that established and oversees the "reasonable cause" standard has taken the position that manufacturers *cannot* condition discounts on 340B compliance and *cannot* demand purchase data from 340B hospitals—exactly what PhRMA admits its member companies wish to do here. It is therefore difficult to understand how a State law barring such preconditions could be an obstacle to HRSA's own compliance and audit processes.

Fourth, the West Virginia court erred by ruling that the enforcement provision in its statute is likely preempted because State actors would be tasked with determining questions of federal law, such as whether a 340B "drug is being diverted to non-[340B] patients in violation of federal law." *PhRMA v. Morrissey*, 2024 WL 5147643, at *16. Even if this were true—and it is not—this Court recently held that

[15] HHS's analysis is precisely the type of agency interpretation that can assist this Court in construing the 340B statute. *See Bondi v. VanDerStock*, 145 S. Ct. 857, 874–75 (2025) ("[T]he contemporary and consistent views of a coordinate branch of government can provide evidence of the law's meaning.").

dual enforcement responsibilities *do not* establish conflict preemption. *Zyla Life Scis.*, 2025 WL 1076889, at *8.

But under no circumstance would a State government official be required to answer federal questions. The Louisiana statute regulates only the *delivery* of a 340B drug that has been purchased by a 340B hospital. The question in any State action to enforce Act 358 is whether the manufacturer refused to deliver a drug purchased by a 340B hospital to a contract pharmacy, not whether that drug was diverted to an ineligible patient. The issue of diversion is completely outside of the scope of the Louisiana law and therefore to this case.

By contrast, the federal 340B statute requires that HRSA determine whether the 340B drug purchase complied with federal law *after the fact* either through an audit or in the *post hoc* Alternative Dispute Resolution process. 42 U.S.C. §§ 256b(d)(2)(B)(iv) & (3). Because the federal statute does not permit drug companies to take the law into their own hands *before delivery* to police suspected diversion,[16] the audit and ADR forums are where questions of diversion would be determined. As such, Act 358 and the federal 340B statute enforce different things and therefore do not raise the possibility of conflicting enforcement decisions. State laws that

[16] *E.g.*, *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113 (2011) (holding that Congress "assigned no auxiliary enforcement authority" to private actors); *Am. Hosp. Ass'n v. HHS*, No. 4:20-cv-08806, 2021 WL 616323, at *6 (N.D. Cal. Feb. 17, 2021) ("Congress made explicit that alleged 340B Program violations are to be first adjudicated by HHS through an established ADR process.").

require drug companies to deliver 340B drugs to contract pharmacies (on the same terms as they deliver to in-house hospital pharmacies) will *never* raise questions of diversion since those will be addressed, per the 340B statute, in the federal processes *after* the drugs have been delivered to those contract pharmacies. There is simply no risk of conflicting determinations about diversion because that determination will be made long after 340B drugs are delivered to contract pharmacies and the narrow legal force of Act 358 (*i.e.*, a delivery mandate) has ceased. Yet again, the district court in this case correctly understood this distinction in a way the West Virginia court did not. *See PhRMA v. Murrill*, 2024 WL 4361597, at *8 ("[T]he Louisiana statute creates an enforcement mechanism, but that mechanism pertains solely to pharmaceutical companies' actions toward pharmacies who enter into contracts with covered entities under the Section 340B program. The Louisiana statute does not address the pharmaceutical companies' agreements with HHS or the pricing, patient definition, or 'double dipping' restrictions addressed in the HHS' enforcement scheme.").

II. ACT 358 IS NOT VOID FOR VAGUENESS.

An economic regulation is invalid "only if it commands compliance in terms 'so vague and indefinite as really to be no rule or standard at all' . . . or if it is 'substantially incomprehensible.'" *Ford Motor Co. v. Tex. Dep't Transp.*, 264 F.3d

493, 507 (5th Cir. 2001) (citing *United States v. Clinical Leasing Serv., Inc.*, 925 F.2d 120, 122 n. 2 (5th Cir. 1991)). That is not the case here.

That Act 358 does not include a definition of "interference" does not render the statute unconstitutionally vague.[17] This is because drug "manufacturer[s] or distributor[s]"—the only entities subject to the provisions' prohibitions—can readily assess what conduct is prohibited by the statute's terms, including the term "interfere." Indeed, countless criminal and civil statutes prohibit "interference" without expressly defining the term. The Supreme Court of Louisiana, for example, rejected a party's argument that the term "interfering" in a State statute was unconstitutionally vague as "plainly without merit" because that term and others "have well understood meanings in the context of their use in the statute." *State v. McCoy*, 395 So.2d 319, 321–22 (La. 1980), *overruled on other grounds*, *State v. Caruso*, 733 So.2d 1169 (La. 1999). And there are numerous examples in the U.S. Code. *E.g.*, 15 U.S.C. § 77kk(c) ("[I]t shall be unlawful for [specified entity] . . . to do any act directly or indirectly which would interfere with or obstruct or hinder or which might be calculated to obstruct, hinder, or interfere with the policy or policies

[17] Black's Law Dictionary defines "interference" as "[t]he act of . . . meddling in the affairs of others" or "[a]n obstruction or hindrance." *Interference*, Black's Law Dictionary (12th ed. 2024). Merriam-Webster defines "interfere" as "to enter into or take a part in the concerns of others," "to interpose in a way that hinders or impedes[,]" or "to act reciprocally so as to augment, diminish, or otherwise affect one another[.]" *Interfere*, Merriam-Webster Dictionary, https://www.merriam-webster.com/dictionary/interfering.

of the said Department of State or the Government of the United States . . ."); 18 U.S.C. § 245(b) ("Whoever . . . by force or threat of force willfully injures, intimidates or interferes with, or attempts to injure, intimidate or interfere with [specified persons] shall be fined . . . or imprisoned . . ."); 29 U.S.C. § 158(a); 29 U.S.C. § 2615(a)(1); 42 U.S.C. § 3617; 47 U.S.C. § 333. Thus, finding the term "interfere" to render Act 358 unconstitutionally vague would have vast repercussions throughout the various civil and criminal codes of Louisiana and the nation.

In any event, it is disingenuous for PhRMA to argue that its members do not understand what is meant by "interference." Louisiana is specifically responding to PhRMA's members' efforts, since 2020, to restrict contract pharmacy arrangements. Drug companies know exactly what the law seeks to prevent. Courts must "interpret the relevant words not in a vacuum, but with reference to the statutory context, 'structure, history, and purpose.'" *Abramski v. United States*, 573 U.S. 169, 179 (2014) (internal citation omitted). And to the extent there is any doubt, Louisiana courts recognize the doctrine of *noscitur a sociis*, under which "general and specific words, capable of analogous meaning, when associated together, take color from each other," meaning that the term "interference" can be considered in the context of the surrounding words "deny," "restrict," and "prohibit." *State v. Hertzog*, 131 So.2d 788, 787 (La. 1961).

Moreover, Act 358 is not, as PhRMA implies, seeking to prevent drug companies from using the federal statute's audit and ADR mechanisms. In fact, the new law explicitly states that it should not be construed or applied to be in conflict with federal law or regulations. *See* § 2886. As noted, the district court understood this. So did the Eighth Circuit when upholding PhRMA's challenge of an analogous Arkansas state law, the ADR mechanisms provided by the 340B statute are wholly separate from the enforcement mechanism of Act 358. "HHS has jurisdiction over different disputes: disputes between covered entities and manufacturers regarding pricing, overcharges, refunds, and diversion of 340B drugs to those who do not qualify for discounted drugs." *PhRMA v. McClain*, 95 F.4th at 1144. In contrast, Act 358 provides that the Louisiana Attorney General enforce Act 358's state-law requirement that drug manufacturers not deny the 340B discount to covered entities that dispense 340B drugs to their patients at contract pharmacies.

CONCLUSION

For these reasons and those set forth in Appellees' Brief, this Court should affirm the district court's judgment.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on April 18, 2025, the foregoing Brief of American Hospital Association, 340B Health, Louisiana Hospital Association, and American Society of Health-System Pharmacists as *Amici Curiae* in Support of Defendant-Appellee was filed electronically and has been served via the Court's ECF filing system in compliance with Rule 25(b) and (c) of the Federal Rules of Appellate Procedure on all registered counsel of record.

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type volume limitations of Federal Rule of Appellate Procedure 32(a)(7)(B) and Local Rule 32(b) because it contains 6,496 words, excluding the parts of the brief exempted by Rule 32(f).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Rule 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word in fourteen-point Times New Roman font.

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